

Apph. No. 10/065,595

Docket No. 125974/GEM-0053

**REMARKS / ARGUMENTS****Status of Claims**

Claims 1-13, 16-30 and 34-40 are pending in the application and stand rejected. Applicant has amended Claims 1, 16 and 38, has cancelled Claims 2, 17-19 and 39-40, leaving Claims 1, 3-13, 16, 18-30 and 34-38 for consideration upon entry of the present Amendment.

Applicant respectfully submits that the rejections under 35 U.S.C. §103(a) have been traversed, that no new matter has been entered, and that the application is in condition for allowance.

These amendments and accompanying remarks were not presented earlier because Applicant did not fully appreciate the nature of the Examiner's position until the Applicant was advised in more detail of the position by the final rejection, which introduced the Ockuly and Liu et al. references. The claim amendments presented herein, which Applicant respectfully requests entry thereof, should require only a cursory review by the Examiner as they include elements presented in earlier examined claims. Accordingly, such amendments should not require further consideration or search.

**Rejections Under 35 U.S.C. §103(a)**

Claims 1-6, 9-13, 16-30, 37 and 40 stand rejected under 35 U.S.C. §103(a) as being unpatentable over Okerlund et al. (U.S. Patent Publication No. 2003/0187358 A1, hereinafter Okerlund) in view of Ockuly (U.S. Patent No. 6,458,107, hereinafter Ockuly).

Claims 1-6, 9-13, 16-28, 30, 37 and 40 stand rejected under 35 U.S.C. §103(a) as being unpatentable over Keidar (U.S. Patent No. 6,650,927, hereinafter Keidar) in view of Subramanyan et al. (U.S. Patent No. 6,782,284, hereinafter Subramanyan), Chen et al. (WO 96/10949, hereinafter Chen) and Ockuly.

Claims 7, 8, 34-36 stand rejected under 35 U.S.C. §103(a) as being unpatentable over Okerlund in view of Ockuly as applied to Claims 1 and 16 above, and further in view of Liu et al. (U.S. Patent Publication No. 2003/0166999 A1, hereinafter Liu).

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Claims 7, 8 and 34-36 stand rejected under 35 U.S.C. §103(a) as being unpatentable over Keidar in view of Subramanyan, Chen and Ockuly as applied to Claims 1 and 16 above, and further in view of Liu.

Claims 38 and 39 stand rejected under 35 U.S.C. §103(a) as being unpatentable over Okerlund in view of Ockuly and Liu.

The Examiner comments that interventional cardiac procedures involving the coronary sinus are old and well known and therefore, modification of the imaging systems which obtain cardiac data to image the coronary sinus would have been obvious to one skilled in the art. Paper 20050601, page 5.

Applicant traverses these rejections for the following reasons.

Applicant respectfully submits that the obviousness rejection based on the References is improper as the References fail to teach or suggest each and every element of the instant invention. For an obviousness rejection to be proper, the Examiner must meet the burden of establishing a prima facie case of obviousness. *In re Fine*, 5 U.S.P.Q.2d 1596, 1598 (Fed. Cir. 1988). The Examiner must meet the burden of establishing that all elements of the invention are taught or suggested in the prior art. MPEP §2143.03.

Additionally, Applicant respectfully submits that the mere fact that references can be combined or modified does not render the resultant combination obvious unless the prior art also suggests the desirability of the combination. *In re Mills*, 916 F.2d 680, 16 USPQ2d 1430 (Fed. Cir. 1990). "[T]o establish obviousness based on a combination of the elements disclosed in the prior art, there must be some motivation, suggestion or teaching of the desirability of making the specific combination that was made by the applicant." *In re Werner Kotzab*, 217 F.3d 1365, 1371, 55 USPQ2d 1313, 1316 (Fed. Cir. 2000) (citing: *In re Dance*, 48 USPQ2d 1635, 1637 (Fed. Dir. 1998); *In re Gordon*, 221 USPQ 1125, 1127 (Fed. Cir. 1984). *There must also be a reasonable expectation of success in modifying or combining the prior art*, determined from the vantage point of the skilled artisan at the time the invention was made. *In re Fine*, 5 USPQ2d 1596, 1598 (Fed. Cir. 1988); *In re Wilson*, 165 USPQ 494, 496 (CCPA 1970); *Amgen v. Chugai*

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*Pharmaceuticals Co.*, 927 USPQ2d 1016, 1023 (Fed. Cir. 1996) (Emphasis added). And, *there must be some degree of predictability in showing the reasonable expectation of success. In re Rinehart*, 189 USPQ 143 (CCPA 1976); MPEP §2143.03 (Emphasis added).

At the outset, Applicant would like to point out that the claimed invention is not directed merely to an imaging system for obtaining data to image the coronary sinus, but is directed to a CT imaging system for generating cardiac image data that uses a protocol specifically for imaging the coronary sinus, post-processing the data to create a 3D model of the coronary sinus, identifying an anatomical landmark in the model and inserting a geometric marker at the landmark in the model, and then making the model with inserted landmarks available for registration with an interventional system, thereby providing a CT imaging system, and method, for use in medical intervention procedure planning involving the coronary sinus.

In view of the amended claims, Applicant respectfully submits that the references cited by the Examiner fall wholly short of teaching such an invention, and fall wholly short of producing the claimed invention that has any reasonable expectation of success of performing as the claimed invention performs.

Regarding Claim 1 and claims dependent from Claim 1

Applicant has canceled Claims 2 and 40, and has amended Claim 1 to now recite, *inter alia*,

*"A computed tomography (CT) imaging system for use in medical intervention procedure planning involving a coronary sinus, comprising:*

*a CT medical scanner system for generating a volume of cardiac image data using a protocol configured for imaging the coronary sinus...*

*a post-processing system... said post-processing system also configured for blending the volume of cardiac image data with the inserted geometric marker into an interventional system for registration therewith, thereby enabling use of the volume of cardiac image data with the inserted geometric marker during an interventional procedure on a patient..."*

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No new matter has been added as antecedent support for the amendment may be found in earlier examined Claims 2 and 40.

Dependent claims inherit all of the limitations of the parent claim.

Regarding Claim 16 and claims dependent from Claim 16

Applicant has canceled Claims 17-19, and has amended Claim 16 to now recite, inter alia,

"A method for generating an image for use in medical intervention procedure planning involving a coronary sinus, comprising:

acquiring a volume of cardiac image data from a *computed tomography (CT) medical scanner using a protocol configured for imaging the coronary sinus;*

managing the volume of cardiac image data *through segmentation for viewing the coronary sinus and associated right atrium;*

...

*creating and exporting a 3D model containing the saved information to an image database, the 3D model including the coronary sinus;*

*importing the 3D model into an operator interface system;*

*registering the 3D model with the corresponding selected anatomical landmark having the inserted geometric marker and the measured viewable parameter; and*

*visualizing the 3D model at the operator interface system with the selected viewable parameters mapped thereon."*

No new matter has been added as antecedent support for the amendment may be found in earlier examined Claims 17-19.

Dependent claims inherit all of the limitations of the parent claim.

Regarding Claim 38

Applicant has yet further canceled Claim 39, and has amended Claim 38 to now recite, inter alia,

"A method for generating an image *for use in medical intervention procedure planning involving the coronary sinus*, comprising:

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determining from an acquired volume of cardiac image data, the cardiac image data having been received using a *computed tomography (CT) medical scanner and a protocol configured for imaging the coronary sinus*, whether an arterial-phase or a venous-phase contrast study is under review;

*dynamically adjusting a segmentation threshold* in preparation for performing vessel tracking of the coronary sinus from the volume of cardiac image data, *thereby enabling the coronary sinus to be tracked for both arterial-phase and venous-phase contrast enhanced studies*;

processing the cardiac image data for viewing, *including viewing of the coronary sinus*;

viewing the cardiac image data in at least one viewable image;

*inserting a geometric marker into the volume of cardiac image data at an anatomical landmark for subsequent visualization, analysis and registration*;

*selecting a viewable parameter in response to the geometric marker at the anatomical landmark*;

saving at least one of at least one viewable image, an anatomical landmark, and a measured viewable parameter, in an image database."

No new matter has been added as antecedent support for the amendment may be found in earlier examined Claim 39.

Regarding the Examiner's Last Paragraph on Page 2 of Paper 20050601

The Examiner alleges that Claims 1 and 16 are obvious and therefore unpatentable over Okerlund in view of Ockuly.

Applicant respectfully disagrees.

The Examiner acknowledges that Okerlund does not disclose imaging the coronary sinus, and looks to Ockuly to cure this deficiency. Paper 20050601, page 2.

Applicant respectfully disagrees that the combination of these references teach each and every element of the claimed invention having the purpose of the claimed invention.

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Applicant submits that not only does Ockuly fail to cure the deficiency of Okerlund, but that the combination of Okerlund and Ockuly also fails to teach the combination of each and every element of *an imaging system configured for blending the volume of cardiac image data having the imaged coronary sinus with an inserted geometric marker into an interventional system for registration therewith, thereby enabling use of the volume of cardiac image data with the inserted geometric marker during an interventional procedure on a patient*, which is now specifically claimed for in Claim 1. Dependent claims inherit all of the limitations of the parent claim.

Applicant also submits that the combination of Okerlund and Ockuly fails to teach the combination of each and every element of a method for generating an image for use in medical *intervention procedure planning involving a coronary sinus*, including acquiring a volume of cardiac image data from a *computed tomography (CT) medical scanner using a protocol configured for imaging the coronary sinus*; managing the volume of cardiac image data *through segmentation for viewing the coronary sinus and associated right atrium*; inserting a geometric marker into the volume of cardiac image data at an anatomical landmark *for subsequent visualization, analysis and registration*; creating and exporting a 3D model containing the saved information to an image database, *the 3D model including the coronary sinus, and registering the 3D model with the corresponding selected anatomical landmark having the inserted geometric marker and the measured viewable parameter*; which is now specifically claimed for in Claim 16. Dependent claims inherit all of the limitations of the parent claim.

The Examiner alleges that it is well known in the art that interventional procedures are performed in the heart whereby the coronary sinus is involved in the procedure, and looks to Ockuly for support thereof. Paper 20050601, page 2.

While Applicant agrees that Ockuly teaches an interventional procedure involving the coronary sinus, Applicant respectfully submits that disclosure of a steerable catheter for insertion into the ostium of the coronary sinus (Ockuly Abstract) is wholly inadequate in its teaching of a system and method for interventional procedure planning that not only involves the coronary sinus but also involves image segmentation, 3D modeling of the

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cardiac image data, inserted geometric markers in the model, and model registration for subsequent use with an interventional system. Applicant submits that Ockuly may teach the interventional procedure, but lacks a teaching of everything else associated with the claimed cardiac imaging method and system that uses cardiac imaging, segmentation and registration in a specified way.

If one skilled in the art were to combine Ockuly with Okerlund as suggested by the Examiner, the resulting combination would fall wholly short of any adequate teaching that would enable one skilled in the art to do only what Applicant has done. As such, Applicant respectfully submits that the combination of Ockuly and Okerlund fails to establish an enabling teaching of the claimed invention and therefore fails to offer any reasonable expectation of success of arriving at Applicant's invention that performs as Applicant's invention performs, and the Examiner has not stated with specificity where such an enabling teaching may be found in the combination of references, and therefore cannot properly combine the references for the purpose of establishing a prima facie case of obviousness.

Regarding the Examiner's First Full Paragraph on Page 3 of Paper 20050601

The Examiner alleges that Claims 1 and 16 are obvious and therefore unpatentable over Keidar in view of Subramanyan, Chen and Ockuly.

Applicant respectfully disagrees.

The Examiner alleges that Keidar discloses a system and method for generating a 3D model for use in cardiac interventional procedure planning, that Subramanyan discloses a method and apparatus for interventional procedure planning with anatomical landmarks and post-processing, that Chen discloses a system and method for anatomical visualization, and the Ockuly discloses the use of a coronary sinus catheter.

Applicant respectfully disagrees that the combination of these references teach each and every element of the claimed invention having the purpose of the claimed invention.

With regard to Keidar, Applicant submits that Keidar teaches a method and apparatus for generating a 3D geometrical map of an anatomical structure *using a probe*

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*Inserted into the anatomical structure* (Abstract), and finds Keidar to describe this method as using a sensor electrically connected to an electromagnetic sensor cable where the sensor is mounted to a catheter, *Inserted into the patient*, and used to transmit mapping signals to a receiver (Column 4, lines 25-49).

Applicant submits that this technique is more commonly known as electroanatomic mapping, and is substantially different from CT imaging, 3D modeling, anatomical landmarking, and model registering for the purpose of interventional procedure planning, as claimed in the instant invention. Where Keidar teaches an *interventional procedure*, the claimed invention discloses an apparatus and method for *interventional procedure planning*, which is substantially different from Keidar. Moreover, Keidar lacks any teaching of anatomical landmarking.

With regard to Subramanyan, Applicant submits that Subramanyan is directed to an apparatus for measuring parameters preparatory to *a stent replacement of an aneurytic blood vessel* in a patient (Abstract), and finds Subramanyan to be absent any teaching of preparing an imaged model for registration with an interventional system *for the purpose of interventional procedure planning*. Applicant also submits that Subramanyan's teaching of an *interventional procedure* on an aneurytic blood vessel is substantially different than an *interventional planning procedure* involving a coronary sinus that drains blood from a moving heart, where the post-processing involving the coronary sinus model must account for blood draining from the heart and the fact that segmentation cannot be done at any random time, but must be synchronized with the cardiac phase, hence the claimed dynamic segmentation of the instant invention.

With regard to Chen, Applicant submits that Chen is directed to a video based surgical targeting system (Object of the Invention) that is absent any consideration of a blood filled vessel (Detailed Description), let alone a highly curvaceous blood filled vessel that moves as the heart moves, such as a coronary sinus. While Chen may disclose a system and method for anatomical visualization, Applicant submits that such a system falls wholly short of teaching an enabling visualization system for a coronary sinus.



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With regard to Ockuly, Applicant has commented above regarding the shortcomings of Ockuly and submits that such shortcomings are equally applicable in this instance.

If one skilled in the art were to combine Keidar with Subramanyan, Chen and Ockuly as suggested by the Examiner, the resulting combination would fall wholly short of any adequate teaching that would enable one skilled in the art to do only what Applicant has done. As such, Applicant respectfully submits that the combination of Keidar with Subramanyan, Chen and Ockuly fails to establish an enabling teaching of the claimed invention and therefore fails to offer any reasonable expectation of success of arriving at Applicant's invention that performs as Applicant's invention performs, and the Examiner has not stated with specificity where such an enabling teaching may be found in the combination of references, and therefore cannot properly combine the references for the purpose of establishing a prima facie case of obviousness.

Regarding the Examiner's Last Paragraph on Page 4 of Paper 20050601

The Examiner alleges that Claim 38 is obvious and therefor unpatentable over Okerlund in view of Ockuly and Liu. Paper 20050601, page 4.

Applicant respectfully disagrees.

Applicant has commented above regarding the deficiencies of Okerlund and Ockuly with respect to the teaching of the instant application, and submits that such deficiencies are equally applicable to the claimed invention of Claim 38.

The Examiner looks to Liu to cure the deficiency of Okerlund and Ockuly with regard to vessel tracking, and alleges that Liu teaches vessel tracking that includes determining whether an arterial phase or a venous phase contrast study is under review. Paper 20050601, page 5.

Contrary to the Examiner's allegation, Applicant submits that Liu is directed to Magnetic Resonance Angiography (Abstract), which is a substantially different technique as compared to the instant invention and uses a totally different modality as compared to the claimed invention. Not only is the method of Liu absent an enabling teaching of the method of the instant invention that uses CT scanning, and therefore absent any

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reasonable expectation of success, but the Liu process as a whole is also absent a teaching of segmentation and registration of the coronary sinus using CT scanning.

If one skilled in the art were to combine Okerlund, Ockuly and Liu as suggested by the Examiner, the resulting combination would fall wholly short of any adequate teaching that would enable one skilled in the art to do only what Applicant has done. As such, Applicant respectfully submits that the combination of Okerlund, Ockuly and Liu fails to establish an enabling teaching of the claimed invention and therefore fails to offer any reasonable expectation of success of arriving at Applicant's invention that performs as Applicant's invention performs, and the Examiner has not stated with specificity where such an enabling teaching may be found in the combination of references, and therefore cannot properly combine the references for the purpose of establishing a prima facie case of obviousness.

Regarding the Examiner's Two Full Paragraphs on Page 4 of Paper 20050601

The Examiner alleges that Claims 7, 8, and 34-36 are obvious and therefor unpatentable over Okerlund in view of Ockuly, and are further obvious and therefor unpatentable over Keidar in view of Subramanyan, Chen, Ockuly and Liu.

Applicant has commented above regarding the deficiencies of the noted references, and submits that such deficiencies are equally applicable with regard to the instant claims, especially in view of Claims 7 and 8 being dependent on Claim 1, and Claims 34-36 being dependent on Claim 16.

Regarding the Examiner's Comment on Page 5 of Paper 20050601 Relating to Criticality or Unexpected Result

The Examiner implies from the noted comment that Applicant has not provided a showing of criticality or unexpected result relating to the specific segmentation technique used, and that such a technique would have been an obvious design choice of known equivalents in the art.

Applicant wholeheartedly disagrees with the Examiner's implication.

At the outset, Applicant submits that in making such implication the Examiner has not identified what known equivalents in the arts are available for replacing the

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segmentation technique of the instant invention with an equivalent segmentation technique that will work as claimed in the instant invention.

At Paragraph [0046] of the Application as originally filed, Applicant states: "By providing the interventionalist with knowledge of the CS [coronary sinus] anatomy *before intervention*, an appropriate interventional procedure suitable for the particular patient can be identified, thereby improving the efficacy of the interventional procedure."

At Figure 3 and the accompanying text at Paragraphs [0037-0041], Applicant describes a segmentation process that automatically establishes the dynamic segmentation threshold value for vessel tracking of the coronary sinus for both arterial and venous-phase contrast-enhanced studies.

Here, the unexpected result is the outcome of the claimed invention itself, which is not taught or suggested by any of the combinations of references set forth by the Examiner. Nowhere in the combinations of references is one skilled in the art taught how to arrive at an imaging system and method for medical intervention procedure planning involving a coronary sinus that employs a segmentation process for automatically determining whether an arterial or venous-phase study is under review. Only from the instant application is such an unexpected result taught.

Regarding Reasonable Expectation of Success

The Examiner relies on Okerlund for disclosure of a method of planning cardiac interventional procedures where post-processing tools are used, relies on Ockuly for disclosure of the use of a coronary sinus catheter in an interventional procedure, relies on Keidar for disclosure of a system and method for generating a 3D model for use in cardiac interventional planning procedures, relies on Subramanyan for disclosure of a method and apparatus interventional procedure planning (such as placement of a stent) using a post-processing system for marker placement, relies on Chen for disclosure of a system and method for anatomical visualization of structures employing an image database, and relies on Liu for disclosure of angiographic imaging including vessel tracking that includes determining whether an arterial phase or a venous phase contrast study is under review. Paper 20050601, pages 2-4.

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If Okerlund and Ockuly were to be combined as suggested by the Examiner (Claims 1-6, 9-13, 16-30, 37 and 40), Applicant submits that the resulting combination would be an apparatus or method for *an interventional procedure*, not an apparatus or method for use in medical *intervention procedure planning*, and not an apparatus or method having all elements of the claimed invention.

If Keidar, Subramanyan, Chen and Ockuly were to be combined as suggested by the Examiner (Claims 1-6, 9-13, 16-28, 30, 37 and 40), Applicant submits that the resulting combination would be a disassociated arrangement of interventional procedures and interventional planning procedures involving a catheter in a coronary sinus, a stent replacement of an aneurytic blood vessel, an electroanatomic map of the heart, and an image database. In combination, Applicant submits the resulting combination does not offer any reasonable expectation of success in performing as the claimed invention performs.

If Okerlund, Ockuly and Liu were to be combined as suggested by the Examiner (Claims 7, 8 and 34-36), Applicant submits that the resulting combination would be an apparatus or method for *an interventional procedure* involving a catheter in the coronary sinus and arterial or venous phase angiographic imaging, not an apparatus or method for use in medical *intervention procedure planning* involving the coronary sinus, and not an apparatus or method having all elements of the claimed invention.

If Keidar, Subramanyan, Chen, Ockuly and Liu were to be combined as suggested by the Examiner (Claims 7, 8 and 34-36), Applicant submits that the resulting combination would be a disassociated arrangement of interventional procedures and interventional planning procedures involving a catheter in a coronary sinus, a stent replacement of an aneurytic blood vessel, an electroanatomic map of the heart, arterial or venous phase angiographic imaging, and an image database. In combination, Applicant submits the resulting combination does not offer any reasonable expectation of success in performing as the claimed invention performs.

If Okerlund, Ockuly and Liu were to be combined as suggested by the Examiner (Claims 38 and 39), Applicant submits that the resulting combination would be a

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disassociated arrangement of *interventional procedures* and *interventional planning procedures* involving a catheter in a coronary sinus and arterial or venous phase angiographic imaging, not an apparatus or method for use in medical *intervention procedure planning* involving a coronary sinus, and not an apparatus or method having all elements of the claimed invention.

In considering the various combinations of references as a whole, Applicant finds the respective combinations to be deficient in their teaching of an apparatus and method for use in intervention procedure planning that involves the coronary sinus, which moves with the heart and has blood content depending on the cardiac phase. In addition, Applicant also finds the respective combinations to be further deficient in their teaching of 3D modeling with anatomical landmarking for the purpose of registering the model with an interventional system.

Applicant submits that not only do the combinations of references lack a teaching of each and every element of the claimed invention that as a whole must unquestionably perform as the claimed invention performs, but also, absent an enabling teaching that offers a reasonable expectation of success arising from the combinations of references, a prima facie case of obviousness cannot be established.

In view of the foregoing, Applicant submits that the References fail to teach or suggest each and every element of the claimed invention and are therefore wholly inadequate in their teaching of the claimed invention as a whole, fail to motivate one skilled in the art to do what the patent Applicant has done, fail to recognize a problem recognized and solved only by the present invention, fail to offer any reasonable expectation of success in combining the References to perform as the claimed invention performs, and discloses a substantially different invention from the claimed invention, and therefore cannot properly be used to establish a prima facie case of obviousness. Accordingly, Applicant respectfully requests reconsideration and withdrawal of all rejections under 35 U.S.C. §103(a), which Applicant considers to be traversed.

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Applicant has amended the claims for presentation in better form for consideration on appeal, and to more clearly reflect Applicant's invention. The claim amendments should only require a cursory review by the Examiner as they include language presented in earlier examined claims.

In light of the foregoing remarks and amendments, Applicant respectfully submits that the proposed amendments and arguments comply with 37 C.F.R. §1.116 and should therefore be entered, and with their entry that the Examiner's rejections under 35 U.S.C. §103(a) have been traversed, and that the application is now in condition for allowance. Such action is therefore respectfully requested.

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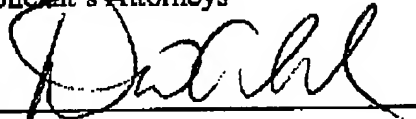
The Commissioner is hereby authorized to charge any additional fees that may be required for this amendment, or credit any overpayment, to Deposit Account No. 07-0845.

In the event that an extension of time is required, or may be required in addition to that requested in a petition for extension of time, the Commissioner is requested to grant a petition for that extension of time that is required to make this response timely and is hereby authorized to charge any fee for such an extension of time or credit any overpayment for an extension of time to the above-identified Deposit Account.

Respectfully submitted,

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